Marking to show changes No new matter

Patent Application

of

Iris G. Zhao

for

GRAFT MATERIAL, DEVICE & METHOD OF MAKING

Reversed bypass with cultured vessel in situ, Artificial autograft, Artificial vessel branch, Vessel budding, Attached new vessel, Extravascular connection, Graft glue, Vessel glue, Graft cuff, Graft wrapping, Graft coating, Graft casting, Vessel cultured in situ, Vessel cuff, Vessel wrapping, Vessel coating, Vessel casting, Laser bypass, Ice anastomosis, Ice bypass, Ice device, Ice graft probe, Water-soluble device, Removable graft device, Blood flow induced vessel, Blood flow induced autograft, Angiogenesis for vessel graft, Angiogenesis for bypass, Neovascularization for vessel graft, Neovascularization for bypass ©®™)

Cross References to Related Applications

This application is a continuation-in-part of application No. 09/589,248, filed June 7, 2000, now Pat. No. 6,84 which is a continuation-in-part of application No. 09/240,832, filed Jul. 20, 1998, now Pat. No. 6,164,281.

BACKGROUND OF THE INVENTION

1. Technical Field

10

20

The present invention relates to an artificial vessel graft system including the material, device, and method of making.

2. Description of the Related Art

Each year, over 600,000 coronary artery bypass surgery are performed worldwide.

Various inventions have been proposed to help the body circulation. For example, US

Patent issued to Miyata et al. # 4,098,571 for heterograft; (to) Chanda et al # 5,645,587 for preventing calcification and degeneration of implanted grafts; (to) Katsuen et al 5,691,203 for serum-free culture of human vascular endothelia cells, to Edelman et al US Pat No. #5,766,584 for inhibiting vascular smooth muscle cell proliferation with implanted matrix containing vascular endothelial cells; (to) Epstein et al # 5,951,589 for expansile device used in blood vessels; (to) Krajicek 5,968,089 for internal shield of a anastomosis; U.S. Pat. No. (U.S. Pa

Besides, it is difficult to sew vessels having a caliber (lumen diameter) smaller than 0.2-1mm. Autografts are not always available. Hetergrafts can cause rejection. Thus, it is desirable to culture an autograft product in situ. This novel technology breaks the lower limitation of vessel caliber requirement. Plus, the invention gets dividing blood flow to reality. The smaller the vessel is, the less pressure and structure difference exists between the artery and vein, and the better the outcome can be.

SUMMARY OF THE INVENTION

20

10

It is a primary object of the present invention to provide a convenient artificial graft system. This system includes a graft material, device and method of making.

A further object of this invention is to provide a reversed bypass from an artery to a vein network through a cultured vessel in situ.

A still further object of this invention is to provide a novel extravascular connection for vessel anastomosis.

What is claimed and desired to be secured by the United States Patent is:

- 1. An artificial graft for sealing and holding a body fluid within a living mammal comprising an adhesive nonpyogenic fluid suitable to form a solid surrounding and sealing a body fluid, and
- (9. (2.) An artificial graft for sealing and holding a body fluid within a living mammal comprising a connection made of a solidable adhesive nonpyogenic material, wherein said connection having a lumen and a wall joined to the lumens and the walls of said two tubular organs respectively.

10

20

- 20 (3) An artificial graft for sealing and holding a body fluid within a living mammal comprising:
- i) a first fluid phase surrounding a body fluid and joining to the adjacent tissue of a body fluid, and
- ii) said first fluid phase turning into a second solid-like phase to support and seal said body fluid.
- 2 (4.) The solidable adhesive nonpyogenic material of claim 1 is disposed around an opening of a tubular organ to support the interior surface cell of said tubular organ spreading out from said opening.
 - 22 [5] The solidable adhesive nonpyogenic material of claim 1 is disposed on the exterior surface of a removable device and a tubular organ suitable to form a solid bond, wherein after removing said removable device, a lumen is formed within said solid bond.
 - 23 [6] The artificial graft of claim 1 comprising a basic matrix made of a blood component from a mammal who will receive said blood component.
- 30 24 [7] The artificial graft of claim 1 comprising fibrin, collagen, trunk cell, stem cell,

umbilical cell, pericyte, endothelium, epithelium, embryo, clone, body fluid composition, or a combination thereof.

- 25 (8) The artificial graft of claim 1 comprising calcium, coral component, alginate, polyethylene, hyaluronate, healon, silicone, acrylic, adhesive peptide, anti-coagulation agent, endothelium adhesion agent, endothelium growth factor, endothelium and epithelium growth hormone, trypsin, vessel dilating agent, collagenase, angiogenesis factor, oxygen microbubble, heparin and analogue, viagra and analogue, adenosine, arginine, alanine, arginine, asparagines, serine, tyrosine, glycine, glutamic acid, valine, isoleucine, cyclohexyl, butyloxycarbonyl, chitosan, sugar, fatty acid, surgical acceptable adhesive, fibroblast growth factor, transforming growth factors α and β, vitreous body component, angiogenin, platelet derived endothelial cell growth factor, angiogenic herb extract, transferrin, laminin, fibronectin, vitronectin, and a combination thereof.
- 26 9. The artificial graft system according to claim 1 further comprising a removable device selected from the group consisting of a laser, ice in a designed shape, water-soluble solid in a designed shape, needle, balloon, and a combination thereof.

20

30

10

- 2/ 10) The removable device of claim 9 is a punch device suitable to make an opening within a solid comprising the vessel wall, organ, tissue, solidable nonpyogenic material, and a combination thereof, wherein approximately 20-100% by volume of blood flow in a donor vessel is flowing into a receiving vessel through said opening.
- 28. [11]. The removable device of claim 9 is a laser device.
- 27 12. The removable device of claim 9 is a needle passing the first wall of a receiving vessel with a core, and thereafter punching the second wall of said

receiving vessel and the first wall of a donor vessel to form a joint opening on the opposite walls of said vessels.

30 13. The removable device of claim 9 is an ice made of saline, body fluid substitute, blood substitute, transfusion solution, pharmaceutical solution, biobeneficial agent, water, or a mixture thereof.

1714. The method of making an artificial graft of claim 1 comprising making an opening on the wall of a tubular organ.

10

7(15). The method of making an artificial graft of claim 1 comprising:

connecting two lumens of two tubular organs through a device, wherein said device is coated by a solidable adhesive material joined to the adjacent tissue of said two lumens, and thereafter,

removing the device to leave a lumen that is connecting said two lumens of said two tubular organs.

- $|\mathcal{E}[16]|$ The method of making an artificial graft of claim 1/comprising:
 - a) selecting an artery and a vein related to same ischemia area,
- b) binding said artery and vein together by a solidable adhesive nonpyogenic material,
 - c) blocking the vein above b), and
 - d) making an opening and lumen on the opposite walls of said vein and artery through said solidable adhesive nonpyogenic material to allow the cover cells from the edge of the opening spreading out on the surface of said lumen to produce a vessel graft in situ.

ABSTRACT

This novel graft system comprises a material, device, and method of making.

The material is a solidable adhesive fluid, suitable to form an extravascular solid solidable bond. The device is selected from ice, laser, balloon, and needle. The method is to making an opening on a vessel wall. Blood flow is used to induce vessel cells to spread out from the opening so that a graft is produced in situ. The best embodiment is a reversed bypass from an artery to a vein network. This system is also useful for repairing tubular gland, ureter, fallopian tube, and lymphduct.

(16) Claims, 7 Drawing Sheets

10